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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,248	10/16/2001	Mark A. Hoffman	CRNC.83071	6008

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Daniel P. Devers
SHOOK, HARDY & BACON L.L.P.
1200 Main Street
Kansas City, MO 64105-2118

EXAMINER	
MORAN, MARJORIE A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/981,248	HOFFMAN ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30,55-60 and 85-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30,55-60 and 85-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 November 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 25-30, 55-60, and 85-90 are pending. All objections and rejections not reiterated below are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

The replacement figure filed 11/8/04 is approved by the examiner.

Claim Rejections - 35 USC § 103

Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000).

Claims 25, 55, and 85 are directed to a computer-implemented method for processing hereditary data, and to a computer system and medium for performing the method wherein the method comprises receiving a genetic test result value for a person, determining if the test result value comprises polymorphic data associated with an atypical clinical event, accessing a list of risk-associated agents, and outputting an "interpretation" of the genetic test result value and the list of risk-associated agents. Claims 26, 56, and 86 limit the method to comprise determining if a patient has been exposed to a risk-associated agent. Claims 27, 57, and 87 limit the method to further comprise accessing an electronic medical record. Claims 29-30, 59-60 and 89-90 limit the method to comprise initiating a clinical action if a patient has been exposed to a risk-associated agent, specifically to inform a clinician to no longer administer the agent.

ICHIKAWA teaches a method for processing hereditary (genetic) data related to response to azathriopine or mercaptopurine (clinical agents) wherein genetic tests results for

individual patients are received, the presence of a polymorphism is determined, wherein particular mutations or polymorphisms are associated with atypical clinical events (side effects) of administration of various drugs, and a decision made to change a drug dosage (p. 523). Since drug dosages are based on the genetic testing results in the method of ICHIKAWA, the method necessarily includes a step of outputting the test results and the list of drugs. ICHIKAWA also teaches that one decision based on the results may be discontinuation of drug use (p. 523, left column). ICHIKAWA does not specifically teach electronic medical records, a computer-implemented method, a computer system or a computer-readable medium.

EVANS teaches association of a variety of drugs with polymorphisms, which are also known to be associated with "idiosyncratic" drug reactions or altered drug sensitivity (p. 489, Table 1), thus teaching a list of "risk-associated agents". It is noted that Table 1 of EVANS includes the drugs and at least one of the polymorphic sites taught by ICHIKAWA. EVANS further teaches automated systems to associate an individual's genotype with polymorphic genes in order to optimize drug administration and disease treatment (p. 490, right column). EVANS does not specifically teach a computer-implemented method nor accessing an electronic medical record.

REINHOFF teaches a computer-implemented method, and a system and computer-readable medium comprising instructions for performing the method, wherein information with regard to a patient's polymorphic profile is linked to degree of response of the patient to a treatment, specifically to side effects; i.e. an "atypical clinical response (paragraphs 33, 38, 57 and 59). REINHOFF also teaches that a variety of electronic medical and/or clinical records may be accessed in his method (paragraph 27).

It would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of ICHIKAWA, as taught by

REINHOFF, and to have accessed a list of treatment/drug options, as taught by EVANS, in the automated method of ICHIKAWA and REINHOFF, where the motivation would have been to facilitate use of the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by REINHOFF (paragraph 59).

Claims 28, 58, and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over ICHIKAWA (Internal Medicine (July, 2000) vol. 39, no. 7, pp. 523-524) in view of EVANS et al. (IDS ref: Science (Oct. 1999) vol. 286, pp. 487-491) and REINHOFF et al. (US 2002/0049772 A1, filed 5/26/2000).as applied to claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-90 above, and further in view of FEY et al. (US Pub. 20020038227, filed 2/26/01).

The claims recite a method, computer system and medium for processing hereditary data, as set forth above. Claims 28, 58, and 88 further limit the electronic medical record to one in a comprehensive healthcare system.

ICHIKAWA, EVANS, and REINHOFF make obvious a computerized method for processing hereditary data, as set forth above. REINHOFF specifically teaches accessing electronic medical records, also as set forth above.

FEY teaches an electronic database for comprehensive/centralized health care management wherein the databases comprise a plurality of clinical information and test results for individuals (paragraphs, 4, 43 and 49).

It would have been obvious to one of skill in the art at the time of invention to accessed the medical records in the method of ICHIKAWA, EVANS and REINHOFF in a comprehensive healthcare system/database, as taught by FEY, where the motivation would have been to associate phenotypic information specific for a patient with genotypic information in a clinical setting in order to better treat/test the patient, as taught by REINHOFF (paragraph 67).

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. In response to the arguments that none of the prior art specifically teaches a computer-implemented method, it is noted that REINHOFF is relied upon for teaching of a computer-implemented method, system, and medium for performing the method, in the rejections above. In response to the argument that the prior art does not teach accessing a list of risk-associated agents in a *computer-implemented* method, it is noted that EVANS does teach a list of "risk-associated agents" for use in a method similar to that claimed, wherein accessing this list in a *computer-implemented* method is made obvious by the combination of references for the reasons set forth above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
2/15/05

Marjorie A. Moran
Primary Examiner
Art Unit 1631